

REMARKS

In the present Amendment, claims 1 and 9 have been amended to recite that the isolated lactic acid bacterial strain is isolated from human stool. Support for the amendment is found, for example, at page 4, lines 31-33 of the specification. Claim 13 has been cancelled without prejudice or disclaimer. Claim 14 has been amended to depend from claim 1. New claim 15 has been added. Support for claim 15 is found, for example, at page 5, line 11 to page 6, line 2 of the specification. No new matter has been added, and entry of the Amendment is respectfully requested.

Upon entry of the Amendment, claims 1, 3-9, 11, 12 and 14 will be pending, of which claims 9, 11 and 12 are withdrawn from consideration.

Request for Correction of Errors in the Specification

The Examiner has requested review of the specification to correct typographical errors. As an example, the Examiner points to the term “garvieae,” which is spelled as “garviaea” in the specification.

However, the term “garvieae” is correctly spelled in the specification. If the Examiner disagrees, the Examiner is respectfully requested to point out the specific location where the term is misspelled.

Response to Provisional Double Patenting Rejection

Claims 4-8 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 1-5 and 6-14 of copending Application No. 12/095,828.

The '828 application was filed December 5, 2006, which is after the filing date of the present application, i.e., June 29, 2004. Pursuant to MPEP § 804(I)(B)(1), in the case of a double

patenting rejection in two co-pending applications, a terminal disclaimer should only be required in the later filed application. Therefore, Applicants respectfully request that the double patenting rejection be withdrawn when it is the only remaining rejection in the present application.

Response to § 112 Rejection, First Paragraph

Claims 1 and 4-8 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

The Examiner states that the claims are broadly drawn to an isolated *L. garvieae* that has an ability to utilize at least one daidzein such as daidzein glycosides, daidzein, and dihydrodaidzein to produce equol. However, the Examiner points to the description of only one strain, i.e., strain *L. garvieae* 20-92, that has this ability. The Examiner also states that there is no guidance in the specification as to reliability and predictability of isolation of further strains of *L. garvieae* using at least one daidzein such as daidzein glycosides, daidzein, and dihydrodaidzein to produce equol and which are non-pathogenic. The Examiner points to paragraphs [0058]-[0065] of the specification. The Examiner's position is that the disclosed strain of *L. garvieae* is not representative of the strains within the species *L. garvieae* having the ability to utilize at least one daidzein such as daidzein glycosides, daidzein, and dihydrodaidzein to produce equol because there is no known correlation between the possession of this property in a single strain and the function of the claimed invention that one of skill in the art would recognize.

Applicants respectfully disagree.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, MPEP 2163.

In the present case, the specification discloses that a strain of the genus *Lactococcus garvieae* having an ability to produce equol from a daidzein compound is isolated from human stool (i.e., *Lactococcus garvieae* 20-92). It is well-known in the art of microbiology that when a particular strain of microorganism is isolated from an environment, many other strains of microorganism that have the same properties as the particular strain and belong to the same species as the particular strain exist in the same or similar environments. This general rule applies to the present invention. Therefore, as the strain of genus *Lactococcus garvieae* 20-92 having the equol-producing ability is isolated from human stool, it is logical and natural for a skilled artisan to believe that many other strains of the genus *Lactococcus garvieae* having the same equol-producing ability exist in human stool, and that such strains can be easily obtained from the environment. If the Examiner takes the position that even though a strain of the genus *Lactococcus garvieae* having the equol-producing ability is obtained, no other strains of the same species exist in the same environment, his position would be against the universal knowledge in the art.

In addition, techniques for isolating microorganisms based on their characteristics had been well-established prior to the priority date of the application. Characteristics of the genus *Lactococcus garvieae* had been known in the art prior to the priority date of the application, and are also disclosed in the specification (page 5, Biochemical Characteristics section). Further, the specification discloses a method of determining the equol-producing ability (for example, Example 1).

Accordingly, those skilled in the art of microorganism-screening techniques would recognize by reading the specification that other strains of *Lactococcus garvieae* can be easily obtained at least from human stool, and that the inventors had possession of not only the

deposited single strain of *Lactococcus garvieae* having the ability to produce equol, but also the whole scope of the claimed invention.

Further, MPEP § 2163 states that “[t]he written description requirement for claimed genus may be satisfied . . . by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties” Applicants submit that each of the biochemical characteristics disclosed at pages 5 to 6 of the specification should be treated as identifying characteristics of strains of *Lactococcus garvieae* having the equol-producing ability.

In view of the above, reconsideration and withdrawal of the §112 rejection are respectfully requested.

Response to § 112 Rejection, second paragraph

Claims 3 and 13 are rejected as allegedly being indefinite. The Examiner states that Claims 3 and 13 are substantial duplicates to the extent that they appear to be directed to the same deposited isolated strain.

Claim 13 is rejected as allegedly being vague, indefinite and confusing, because of the claim limitation “belonging to the genus *Lactococcus* as deposited under FERM BP-10036.”

Claim 13 has been cancelled, rendering the above two rejections moot.

Response to § 102(b) Rejections

Claim 14 is rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Villani et al. (*J. Appl. Microbiol.* 2001, 90, 430-39).

Claim 14 is rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Fortina et al. (*Food Microbiol.* 2003, 30, 397-404).

Claim 14 is rejected under 35 U.S.C. § 102(b) as being anticipated by Paludan Muller et al. (*International J. of Food Microbiol.* 73 (2002) 61- 70).

Claim 14 has been amended to depend from claim 1. Claim 1 is not subject to any of the above three rejections. Accordingly, withdrawal of all the §102(b) rejections is respectfully requested.

Response to § 103(a) Rejection

Claims 1, 4-8 and 13-14 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Villani or Fortina or Muller in view of Setchell *et al.* (US 7,396,855, “Setchell”) and Elliott *et al.* (Journal of Clinical Microbiology, 1991, 29(12): 2731-2734, “Elliott”).

Applicants submit that this rejection should be withdrawn because the cited references do not disclose or render obvious the present invention, either alone or in combination.

The Examiner states that each of Villani or Fortina or Muller discloses isolated strains of a strain of *L. garvieae*. The Examiner admits that the references differ from the presently claimed invention because the references do not teach that the strains have an ability to utilize at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein to produce equol. The Examiner relies on Setchell and Elliott to cure this deficiency in Villani, Fortina and Muller.

The Examiner states that Setchell discloses a composition comprising a strain of *Lactococcus* which appears to have “an ability to utilize at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein to produce equol.” See, for example, Example 5, which contains soy milk, daidzein and equol. The Examiner also states that Setchell differs from the presently claimed invention because the strain disclosed by Setchell is classified as *L. lactis* rather than *L. garvieae*.

The Examiner relies on Elliottt to show that the classification boundaries between *L. lactis* and *L. garvieae* are not clearly defined. The Examiner states that the close taxonomic status demonstrates that the species are clearly closely related, as evidenced also by their capabilities regarding the biotransformation of daidzein and related compounds into equol in compositions such as milk, and soy milk in particular.

Applicants respectfully disagree.

It is very likely that the *Lactococcus lactis* recited in Example 5 of Setchell does not possess the ability to produce equol from a daidzein compound for at least the following reasons.

The Examiner seems to interpret Example 5 of Setchell to indicate that a mixture of microorganisms including *Lactococcus lactis* actually produced equol. However, Example 5 of Setchell merely indicates that daidzein content is lowered when daidzein-rich soy milk is inoculated with the mixture of microorganisms and incubated (column 25, last four lines). Therefore, it is not clear whether equol was actually produced by the mixture of the microorganisms.

The conversion of daidzein to equol involves three steps: daidzein → dihydrodaidzein → tetrahydrodaidzein → equol. Accordingly, the mere reduction of daidzein content does not automatically mean that equol is produced. It may mean that only dihydrodaidzein and/or tetrahydrodaidzein is produced.

Further, the mixture of microorganisms contains five microorganisms other than *Lactococcus lactis*. Therefore, it is not clear which microorganism was involved in metabolizing daidzein.

In view of the above, Applicants maintain that one of ordinary skill in the art would have reasonably believed that the *Lactococcus lactis* of Example 5 of Setchell does not possess the equol-producing ability.

In addition, with due respect, the Examiner's interpretation of the teachings of Elliott is not correct.

While Elliott teaches that some conventional methods were not able to adequately differentiate between *L. lactis* and *L. garvieae*, it also teaches that methods to accurately identify *L. lactis* and *L. garvieae* existed prior to its publication, such as the DNA-DNA-homology method, and partial rRNA sequencing (page 2733, right column, fourth paragraph). Additionally, they provide a simple new method utilizing soluble whole-cell protein profiles to accurately differentiate between *L. lactis* and *L. garvieae* (supra). Accordingly, Elliott does not teach that the classification boundaries between *L. lactis* and *L. garvieae* are not clearly defined; rather, it teaches that *L. lactis* and *L. garvieae* have been distinguishable and can easily be distinguished using their new protocol.

Furthermore, given that Elliott was published more than a decade before the application date of Setchell, Applicants assert that one of ordinary skill in the art would have reasonably assumed that Setchell used a method that allowed them to accurately distinguish between *L. lactis* and *L. garvieae*.

In view of the above, the present claims are not obvious and are patentable over the cited references, either alone or in combination. Reconsideration and withdrawal of the §103(a) rejection are respectfully requested.

Allowance is respectfully requested. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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